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⑦ Applicant: DAIG CORPORATION
14901 Minnetonka Industrial Road
Minnetonka, MN 55345(US)

⑦ Inventor: Fleischhacker, John J.
16631 Meadowbrook Lane
Wayzata, MN 55391(US)
Inventor: Sutton, Greg S.
10608 Rhode Island Ave. N.
Brooklyn Park, MN 55445(US)
Inventor: Krueger, Mark D.
8249 W. River Road
Minneapolis, MN 55444(US)

⑦ Representative: De Minvielle-Devaux, Ian
Benedict Peter et al
CARPMAELS & RANSFORD 43, Bloomsbury
Square
London WC1A 2RA(GB)

⑥ Universal hemostasis cannula.

⑦ Disclosed herein is a hemostasis valve which is formed of a longitudinally extended valve housing having a first opening and a central longitudinal passage communicating with an opposite second opening. A cap means is provided for enclosing the first opening of the housing, said cap means having a hole to permit insertion of a catheter. Also provided is a one-piece seal means located within the longitudinally extended housing, said seal means comprising a sealing neck having a relatively small opening therein and communicating with a sealing chamber having opposing sealing exit lips which are both readily expandable to a diameter less than that of the valve housing upon insertion of a catheter.

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UNIVERSAL HEMOSTASIS CANNULA

(d) Background of Invention

1. Field of Invention

This invention relates to hemostasis valves. More particularly, this invention relates to a universal hemostasis valve which is useful with a variety of catheters having a wide range of diameters.

2. Prior Art

The introduction of catheters into blood vessels for a variety of purposes such as coronary angiography has been known for many years. Several techniques for introducing these catheters are available. One such technique is the cut-down method. Another is the Seldinger technique. This technique involves surgically opening a vein or artery with a needle, inserting a guidewire into the vein or artery through the lumen of the needle, withdrawing the needle, inserting over the guidewire a dilator located inside an associated hemostasis valve and sheath, removing the dilator and inserting a catheter through the hemostasis valve and sheath and into the blood vessel.

Various types of hemostasis valves have been known in the prior art. However, in most cases hemostasis valves are designed for use with a particular size of catheter. Because adequate sealing around the catheter walls cannot be obtained for a wide variety of catheters having a range of diameters, it has not been possible in the past to employ a single hemostasis valve with catheters of widely varying diameters.

This problem is particularly acute when the guidewire technique is used. Guidewires are of extremely small diameters -often less than .050 inch. However, many catheters are relatively much larger in diameter. Therefore, in the prior art it has been difficult to design a hemostasis valve which will seal around both relatively large diameter catheters as well as relatively small diameter guidewires.

Prior art hemostasis valves have, in many instances, been of the gasket sealing type such as, for example, those shown in U.S. Patent No. 4,000,739 which employs two gaskets to seal against the back pressure of blood in the cannula unit. The first, donut-shaped, gasket is provided with a hole slightly smaller than the diameter of the catheter to be inserted, while the second gasket is provided with a Y-shaped slit. When guidewires or

catheters which are too small in diameter are inserted into this hemostasis valve, the sealing advantages of the first, donut-shaped gasket are no longer available because the larger diameter "donut holes" will not seal around the smaller diameter guidewire or catheter. Moreover, when catheters are employed having diameters which are extremely large in relation to the diameter of the hole in the donut-shaped gasket, the gasket may become separated from the hemostasis valve body or it may be unduly stretched so that it will not seal properly when a smaller sized catheter is inserted at a later time.

Hemostasis valves having similar problems are also disclosed in U.S. Patent Nos. 4,673,393 and 4,610,665.

U.S. Patent No. 4,436,519 discloses a combination of a donut-shaped gasket and a second cup-shaped seal. Like the prior art, two gasket hemostasis valves described above, the device described in the '519 patent suffers the same deficiencies because its donut-shaped gasket can only accept catheters having a relatively limited range of diameters. Moreover, this device is particularly susceptible to leakage when only the guidewire is in place.

U.S. Patent No. 4,655,752 discloses a surgical cannula which does not employ donut-shaped gaskets. However, this cannula, like the other prior art cannulas, suffers from a lack of universality and from poor sealing. While two seals are employed, the second seal may only be used with catheters having a limited range of diameters and will provide little or no sealing for a guidewire.

Another problem shown by many prior art hemostasis cannulas is that the surgeon must be able to "feel" the catheter as it is inserted through the gaskets or other sealing members of the hemostasis valve and ultimately into a blood vessel. If insertion of the catheter through the hemostasis valve is too difficult, the cannula unit may be rejected by surgeons as being difficult to use during catheter insertion. Concomitantly, the use of hemostasis valves which exert undue pressure on the side walls of inserted catheters may lead to excessive hemodynamic dampening of the catheter. In other words, excessive pressure on the exterior side-walls of a catheter may cause a narrowing of the catheter's diameter thereby altering measurement parameters within the catheter.

Thus, it is important in providing a sealing mechanism for a hemostasis valve unit that the mechanism:

1. be universal, i.e., useful with both guidewires and with catheters having a wide range of diameters;
2. provide for relatively easy insertion of all diameters of catheters; and
3. be free from excessive restriction which would cause hemodynamic dampening.

German Patent No. 3,042,229 purports to describe a hemostasis valve which may be used with catheters having a variety of diameters. However, it is extremely difficult to use this valve when relatively large diameter catheters are employed because the second seal, as shown in the patent, is required to expand against the sidewalls of the cannula, thereby, significantly increasing friction during insertion and the risk of hemodynamic dampening. Moreover, the sealing means of the device described in the '229 patent is formed from two separate pieces thereby increasing the difficulties of manufacture and the likelihood that one of the seals may become dislodged particularly during use with large sized catheters.

Accordingly, it is an object of this invention to prepare a hemostasis valve unit.

Another object of this invention is to prepare a hemostasis valve which is universal in nature and may be used with a wide variety of both large and small diameter catheters, without leakage.

It is another object of this invention to prepare a hemostasis valve which will not leak when it is inserted into a vein or artery over a guidewire.

It is a further object of this invention to prepare a hemostasis valve having a unitary sealing member forming at least two separate sealing sections.

It is yet another object of this invention to construct a hemostasis cannula unit which will permit the use of catheters having a wide variety of diameters, while at the same time allowing insertion of any of these catheters without undue pressure/friction thereby providing good surgical "feel" for all diameters of catheters and reduced hemodynamic pressure dampening.

These and other objectives are obtained by constructing the hemostasis cannula units of the instant invention.

(e) Summary of Invention

The instant invention involves a hemostasis valve which includes a longitudinally extended housing having first and second opposing open ends; a cap means enclosing the first end and having an opening to permit insertion of a dilator or catheter into the longitudinally extended housing; and a one-piece seal means located within the central passage of the longitudinally extended

housing. The seal means is provided with a sealing neck and sealing exit lips arranged so that a catheter may be readily inserted through the sealing neck and out the sealing exit lips. The second end of the valve housing is attached to a sheath which is inserted into the vasculature.

By employing this hemostasis valve, it is possible to use different catheters which may vary in diameter. At the same time surgeons who use the universal hemostasis valve of the instant invention find that it has excellent "feel" and a reduced incidence of hemodynamic pressure dampening, for a wide range of catheters diameters. Finally, the cannula of the instant invention is particularly useful because it provides for good sealing, even around relatively small diameter catheters and guidewires.

(f) Brief Description of the Drawings

Figure 1 is a cross-sectional view of a hemostasis valve according to the instant invention.

Figure 2 is a bottom view of the one-piece, seal means of the instant invention.

Figure 3 is a top view of the seal means of the instant invention.

(g) Detailed Description of Invention

Turning first to Figure 1 which shows a cross-sectional view of the hemostasis cannula unit of this invention, the cannula unit (1) is formed from four major parts. The first is the cap means (2) which is attached to the top of the longitudinally extended, valve housing (3). The valve housing has first (21) and second (22) opposing open ends to permit insertion of a catheter into and out of the interior of the valve housing (3). The cap means (2) and the valve housing (3) are formed from a relatively hard plastic such as high density polyethylene. The cap means may be secured to the body by gluing or heat sealing, but preferably is mechanically attached to the body using threads, clips or, as shown in the drawings, by snap fittings (4) and (5). The third major element of the hemostasis cannula unit of the instant invention, the one-piece seal means (6), is formed from a pliant, resilient, rubber such as silicone rubber or latex rubber, which can be shaped to readily admit passage of catheters. The final major element of the hemostasis cannula unit of the instant invention is a tube sheath (7) which is formed from a relatively rigid plastic such as teflon or polyethylene. The sheath is inserted within the valve housing (3) and cooperates to provide an exit from the interior of the valve housing (8).

As shown in Figure 1, the seal means (6), the

cap means (2) and the valve housing (3) are joined together by inserting the seal means (6) into the cap (2) such that the upper most edge of the seal means (9) is fully inserted within the cap and rests against the rib (10), which is preferably circular in nature. The cap (2) with the seal means (6) in position is then placed on top of the valve housing (3), the seal means (6) is inserted inside the valve housing (1), and downward pressure is applied to the cap means (2) thereby forcing the snap fitting (4), which is a circular ridge within the cap means, into engagement with the corresponding groove (5) on the valve housing. With the fittings (4) and (5) engaged, downward pressure on the cap (2) is maintained causing compression of the upper most edge (9) of the seal means (6) by the rib (10) which serves to hold the seal means (6) in place within the valve housing (3).

The cap means (2) is provided with an opening (12) at the top, preferably in the form of a Luer taper which can receive a corresponding male Luer taper located on the proximal end of a dilator (not shown) that is inserted within the hemostasis cannula unit for purposes of introduction into body vessels.

The seal means (6) has a conical receiving area (13) which tapers into a sealing neck having a neck opening (14). Taken together the conical receiving area (13) and neck opening (14) provide for easy insertion of a catheter into the seal means and through the neck opening (14), with good "feel" and a minimization of hemodynamic pressure dampening.

In order to insure that when a catheter is inserted through the sealing neck undue expansion of the sealing neck against the side walls of the valve housing does not occur, it is necessary to provide the seal means with a waist (23) which approximately mirrors the internal shape of the sealing neck so that a relatively constant wall thickness is maintained in the sealing neck area. As a result when a catheter is inserted through the neck, the neck area will not unduly bulge out, and come into contact with the walls of the valve housing. In this way excess friction upon insertion of large catheters is avoided. In the prior art, catheters often caused sealing means to expand and contact the valve housing walls thereby increasing friction and pressure on the catheter, and making insertion and use more difficult.

Communicating with the conical receiving area (13) and the neck opening (14) is a sealing chamber (15) which may be of any convenient shape, although preferably, it is semi-spherical or flatten spherical in shape. The interior diameter of the chamber (15) is preferably the same as the largest outside diameter of any catheter which will be employed with the hemostasis cannula unit of this

invention. The diameter of the neck (14) which leads into the chamber (15) should be slightly smaller than that of any guidewire which will be employed so as to provide for sealing against the reverse flow of blood which may enter into the chamber (15) while a guidewire is in place in the cannula unit.

A second seal is provided in the seal means by virtue of at least a pair of sealing lips (16) and (17) located in the area of the flattened portion of chamber (15), located opposite from the neck opening (14). Preferably these lips are provided by means of a single linear slit (20) in the flatten section of the semi-spherical sealing chamber walls, which slit is generally perpendicular to the main axis of the valve unit.

The single slit (20) and the lips (16) and (17) may be forced open by a dilator or catheter inserted into the body of the hemostasis cannula unit and through the seals means (6). The spacial geometry of the walls of the semi-spherical sealing chamber (15) strongly force opposing sealing lips (16) and (17) into a normally closed position and hold them in that position to prevent an external reverse flow of blood. Likewise, when the sealing lips (16) and (17) are opened after a catheter is inserted, the opposing forces of neck (14) will seal around the catheter and halt and reverse flow of blood.

The sealing lips which are shown in the form of a pair of opposing lips (16) and (17) may also take the form of three or four separate lips formed from either "y" or "cross" shaped slits. However, two lips are preferred because they provide the maximum amount of sealing pressure from the semi-spherical walls of the sealing chamber when a catheter is not in place in the hemostasis cannula unit.

The outside diameter of the chamber (15) should be less than the diameter of the longitudinally extended hemostasis valve housing so as to insure that, even upon insertion of a catheter into the seal means (6), the body of the seal means (6) will not expand against the interior walls of the valve housing thereby increasing the difficulty of catheter insertion and the likelihood of hemodynamic pressure dampening.

The valve housing itself (3) is longitudinally extended to form a valve chamber (8) having first (21) and second (22) openings which allow a catheter to be inserted through the chamber. Preferably access to the interior to the chamber is also provided through a port (9) to which is attached a barbed fitting (10) that facilitates attachment of tubing to permit insertion or withdrawal of fluids from the chamber (8) during use.

The valve housing of the hemostasis cannula unit is also provided with a suture ring (18) to allow

temporary attachment of the cannula unit directly to a patient's body to provide stabilization of the hemostasis cannula unit.

The final element of the hemostasis cannula unit of the instant invention is the sheath (7) onto which the valve housing (3) may be attached. The sheath preferably is provided with a tapered distal tip (8), in the preferred use to closely fit onto a dilator which is inserted through the cannula for initial introduction into a body vessel.

In the preferred means of operation, a needle is inserted into a patient's blood vessel. Through the lumen of the needle a guidewire is in turn inserted into the blood vessel. The hemostasis cannula unit of the instant invention is then prepared by inserting a dilator through the cap opening (12), the seal means (6), out the opening (24) through the sheath (7) and out the distal end of the sheath. The sheath (7) and dilator are designed such that the tapered section (19) snugly fits around the dilator. Preferably the proximal end of the dilator is provided with a male Luer fitting to engage with the female Luer fitting in the cap opening (12).

The dilator and hemostasis cannula unit are advanced as a unit onto the guidewire and into the blood vessel. The dilator tip, which is tapered, increases the size of the opening in the blood vessel as it enters the vessel so that ultimately an opening large enough to accommodate the sheath (7) is formed. After the sheath is inserted into the blood vessel, the dilator is removed, leaving in place the hemostasis cannula unit of the instant invention with the guidewire protruding therefrom sealed by neck (14).

With the hemostasis cannula unit, thus in place, it is possible to insert catheters having a wide range of diameters with ease. The catheter is inserted through the hole (12) in the cap means (2) and into the seal means (6). If the catheter is inserted slightly off center it will be guided to the neck opening (14) by means of the conical receiving area (13). The catheter is then moved into the semi-spherical valve chamber (15) and out through the sealing lips (16) and (17). After exiting through the sealing lip (16) and (17), the catheter is advanced out the opening (24) down through the sheath (7) and into the blood vessel. Any blood which flows between the sheath and the catheter and up into the interior of the valve body (8) is not permitted to escape to the exterior because of the sealing action of neck (14) around the body of the catheter.

In Figure 2, which is a bottom view of the seal means of the instant invention, the sealing lips (16) and (17) are shown along with the slit (20).

In Figure 3, which is a top view of the seal means of the instant invention, the conical receiv-

ing area (13) of the seal means (6) is illustrated along with the hole (14).

The present embodiment of the instant invention is considered to be merely a illustrative and changes may be made in its specific form without departing from the spirit or essential characteristics of this invention.

10 **Claims**

1. A hemostasis cannula unit comprising:

(a) a longitudinally extended valve housing having a first opening and a central longitudinal chamber communicating with a second opening;

(b) a cap means enclosing the first opening of the valve housing and providing a hole to permit the insertion of a catheter into the housing's first opening through the central chamber and out the opposite second opening; and

(c) a one-piece seal means located within said central chamber and having a sealing neck and sealing exit lips such that a catheter may be inserted through the hole in the cap means, the sealing neck and the sealing exit lips and out the second opening of the longitudinally extended housing, wherein the sealing neck is readily expandable upon insertion of a catheter to a diameter of less than the internal diameter of the valve housing and said sealing exit lips are formed of at least a pair of opposing, normally closed lips.

2. The hemostasis cannula unit of Claim 1 wherein the valve housing includes an exit port providing access to the central chamber.

3. The hemostasis cannula unit of Claim 1 wherein the sealing lips are formed from a slit in a flattened section of a semi-spherical valve sealing chamber, said slit being generally perpendicular to the axis of the longitudinally extended valve housing.

4. The hemostasis cannula unit of Claim 1 wherein the sealing neck has an opening having a diameter slightly less than that of a guidewire.

5. The hemostasis cannula unit of Claim 1 wherein the sealing neck is adjacent the cap means.

6. The hemostasis cannula unit of Claim 1 wherein the seal means is provided with a conical receiving area which is tapered into the sealing neck and wherein the sealing neck is provided with a waist which mirrors the internal shape of the sealing neck so that a relatively constant wall thickness is maintained in the sealing neck area.

7. The hemostasis cannula unit of Claim 1 in combination with a sheath means.

8. The hemostasis cannula unit of Claim 7 wherein the sheath means is tapered at the distal end.

9. A one-piece hemostasis valve seal means for location within the central passage of a hemostasis valve housing comprising sealing neck and sealing exit lips wherein the sealing neck is readily expandable upon insertion of a catheter to a diameter less than the internal diameter of the valve housing and wherein the sealing exit lips are formed of at least a pair of opposing, normally closed lips through which a catheter may be inserted.

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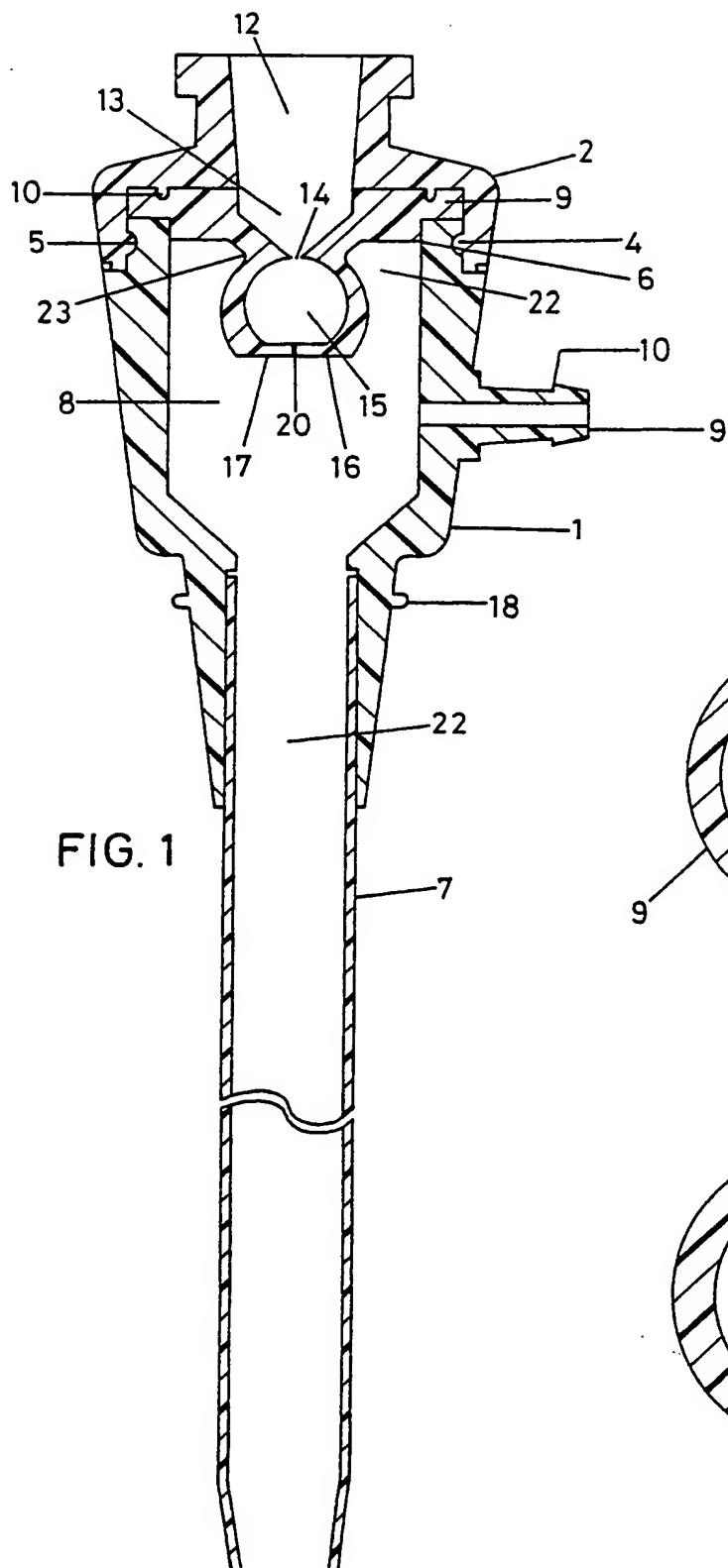
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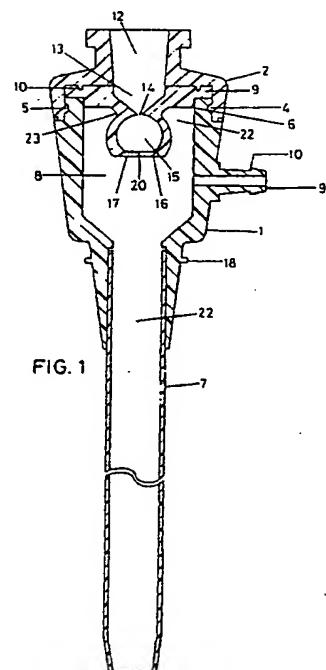
⑲ Applicant: DAIG CORPORATION
14901 Minnetonka Industrial Road
Minnetonka, MN 55345(US)

⑳ Inventor: Fleischhacker, John J.
16631 Meadowbrook Lane
Wayzata, MN 55391(US)
Inventor: Sutton, Greg S.
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EUROPEAN SEARCH REPORT

Application Number

EP 88 31 0142

| DOCUMENTS CONSIDERED TO BE RELEVANT | | | |
|--|---|--|--|
| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (Int. Cl. 4) |
| D, Y | US-A-4 655 752 (G.P. HONKANEN et al.) * claim 1; figures 2,4,5 * | 1,2,7-9 | A 61 M 5/14 |
| A | --- | 4-6 | A 61 M 25/00 |
| Y | US-A-4 424 833 (K.A. SPECTOR et al.) * claims 1,5,6; figures 2-4 * | 1,2,7-9 | |
| A | --- | 3 | |
| A | EP-A-0 230 751 (WELCH ALLYN INC.) * claims 1,2; figures 1,4,5 * | 1,3,6,9 | |
| | ----- | | |
| The present search report has been drawn up for all claims | | | |
| Place of search | Date of completion of the search | Examiner | |
| BERLIN | 29-01-1991 | ROLAND A T | |
| CATEGORY OF CITED DOCUMENTS | | T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons A : member of the same patent family, corresponding document | |
| X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document | | | |